FDA Acts to Prevent More Drug Shortages

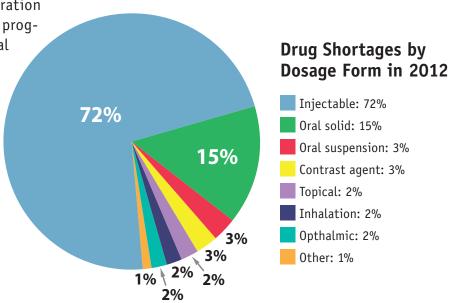
he Food and Drug Administration (FDA) has made significant progress in assuring that critical medicines are readily available, preventing 282 threatened shortages in 2012 compared to 38 in 2010. Additionally, the agency is determined to do even more to make sure that drug shortages do not interfere with patients' access to critical medications.

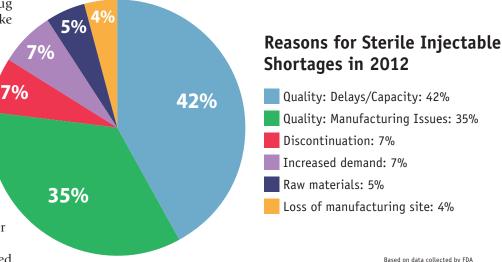
FDA has released a strategic plan that outlines the tools the agency currently has available to prevent or resolve a shortage and details long-term solutions. Actions that drug manufacturers and others can take are also detailed in the plan.

In addition, FDA has issued a proposed rule requiring manufacturers of certain medically important drugs to give FDA notice if they intend to discontinue making a drug or learn of manufacturing problems that are likely to affect supply.

Previously, notice was required only from manufacturers of certain critical drugs that were not made by one or more other companies.

In 2011, President Obama issued an Executive Order emphasizing the importance of notification in helping FDA prevent drug shortages. Within six months, FDA saw a six-fold increase in voluntary notifications from manufacturers. Those notifi-





cations contributed to the agency's ability to take preemptive actions that reduced last year's shortages to less than half that of the year before.

In July 2012, Congress broadened

and deepened reporting requirements. Consistent with the new law, FDA is proposing to require that all manufacturers of certain medically important drugs give FDA at least six months' notice, or as far in advance as practical, if they intend to discontinue making the drug or learn of manufacturing problems that are likely to affect supply.

Additionally, the rule would impose the same requirement on manufacturers of certain medically important biological products, which include therapies made from living organisms (such as cells) rather than the chemical compounds used in drugs.

"We cannot singlehandedly prevent all shortages: We can't force a private company to continue making a drug, and FDA does not have manufacturing ability to make the drugs ourselves," said Valerie Jensen, R.Ph., a pharmacist and associate director of FDA's Drug Shortage Program.

"However," she added, "we are working with industry and using every available tool to address the problem."

Extent of the Problem

Nearly half of all Americans take at least one prescription drug in a given month, and about 3 billion drugs are ordered each year, according to the Centers for Disease Control and Prevention (www.cdc.gov/nchs/fastats/drugs.htm).

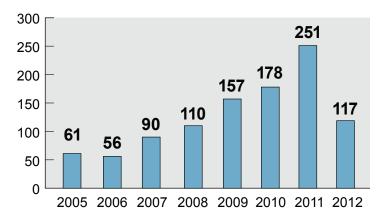
By comparison, the number of medicines in short supply may seem small, but each one can be essential to the life of a patient who needs it. Many of the medicines in short supply are for critically ill patients. Moreover, until last year, the shortages kept increasing.

In 2006, 56 drugs were in short supply. The number grew every year until it reached a record high of 251 drugs in 2011. Then, in 2012, the number dropped, to 117. Numbers for 2013 are not yet available.

"While we were happy to see a drop last year, we must work ever more diligently to make sure the trend continues in the right direction," said Jensen.

More than 70% of supply problems involve sterile drugs injected into the body. Shortages have affected cancer drugs, anesthetics, "crash cart" drugs used in emergencies, and electrolytes

U.S. Drug Shortages by Year from 2005 to 2012



Based on data collected by FDA

for patients being fed intravenously.

Among the shortages addressed last year: a cancer drug used to treat child-hood leukemia and osteosarcoma and a drug used for ovarian and other cancer regimens.

Manufacturing issues involving quality or capacity are the most common reasons for drug shortages. These issues can be particularly problematic for sterile injectable drug products, which require a highly specialized manufacturing process. Other factors include a lack of raw materials, increased demand, and a company's business decision to stop making some older, less profitable drugs.

FDA's Role

FDA officials are working closely with industry, health care providers and patients.

When the FDA gets advance warning that a shortage could occur, responses include working with other firms that make or could make the drug to see if they can start or ramp up production. If so, the agency works to expedite inspections and reviews so manufacturers can start or step up production of a scarce product.

The cooperation of industry is critical. Among suggestions made by FDA: building a robust inventory before making major manufacturing changes, getting up-to-date information from contractors, designing an

allocation plan in advance in case a shortage occurs.

The agency is currently considering an incentive program which would recognize manufacturers who help address a shortage.

The strategic plan was developed by FDA's Drug Shortages Task Force, which includes experts from multiple centers and offices within FDA.

What to Do?

If a drug you're taking is not available and you believe it might be in short supply:

- Visit FDA's Current Drug Shortages page to see if it has been reported in short supply: www.fda.gov/Drugs/DrugSafety/ DrugShortages/ucm050792.htm
- If your drug isn't on the list, send the name and dose of the drug and your contact information to *drugshortages@fda.hhs.gov*.
- If your medicine is in short supply, talk with your doctor. There may be alternatives available.

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